St. Jude Medical Physician's Manual

SJM Biocor® Valve

(Symbols)
Serial Number
Use Before Date
Model Number
Single Use Only
Processed Using Aseptic Technique
Long Term Storage/Do Not Refrigerate
Mfg. Date
Consult Instructions for Use
Manufacturer
Authorized European Representative

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CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

1. DEVICE DESCRIPTION

The SJM Biocor® valve, Figure 1, is a triple composite bioprosthetic heart valve manufactured from select porcine aortic valve cusps. The cusps are carefully matched for optimum leaflet coaptation and hemodynamics. Only cusps devoid of the septal muscle bar are utilized in the fabrication of the valve.

Following tissue fixation, the tissue is mounted on a polyester-covered flexible acetal copolymer stent. The stent is a low profile design with a scalloped shape permitting supra-annular placement of the sewing cuff and intra-annular placement of the inflow edge of the valve.

For radiopaque visualization, the valve contains a wire within the sewing cuff.

The SJM Biocor® valve is fabricated with a bovine pericardial sheath. The pericardial sheath is attached directly to the outflow edge of the valve thereby protecting the leaflets as they open and close. The pericardial sheath and the porcine valve cusps are preserved and crosslinked in a glutaraldehyde solution. Glutaraldehyde, formaldehyde and ethanol are used in the valve sterilization process.

The SJM Biocor® valve is supplied sterile and non-pyrogenic.

See Table 1 for model number descriptions and reference dimensions:

Table 1: Model Number Descriptions and Reference Dimensions

Model Number	Tissue Annulus Diameter (mm)	Aortic/Ventricular Protrusion (mm)	Total Height (mm)
Aortic Heart Valves			
B10-21A-00	21	9	14
B10-23A-00	23	9	15
B10-25A-00	25	10	16
B10-27A-00	27	11	17
Mitral Heart Valves			
B10-27M-00	27	9	17
B10-29M-00	29	10	19
B10-31M-00	31	10	20
B10-33M-00	33	11	20

Figure 1 - Aortic and Mitral Valves

2. INDICATIONS FOR USE

The SJM Biocor® valve is intended as a replacement for a diseased, damaged, or malformed aortic or mitral native heart valve. It may also be used as a replacement for a previously implanted aortic or mitral prosthetic heart valve.

3. CONTRAINDICATIONS

None known.

4. WARNINGS AND PRECAUTIONS

4.1 Warnings

- Valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Model B805 or B807 sizers for sizing of SJM Biocor® valves.
- Accelerated deterioration due to calcific degeneration of the SJM Biocor® valve may occur in:
  - Children, adolescents, or young adults
  - Patients with altered calcium metabolism (e.g., patients with hyperparathyroidism or chronic renal failure)
  - Individuals requiring hemodialysis
- For single use only.
- Do not resterilize the valve by any method.
- Passage of a catheter or transvenous pacing lead through any bioprosthesis may damage the valve and is therefore not recommended.

Do not use if:

- The valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration;
- The expiration date has elapsed;
- The tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging; or
- The storage solution does not completely cover the valve.

4.2 Precautions

- The safety and effectiveness of the SJM Biocor® valve have not been established for the following specific populations:
  - patients who are pregnant
  - nursing mothers
  - patients with chronic renal failure
  - patients with aneurysmal aortic degenerative conditions, e.g., cystic medial necrosis, Marfan's syndrome
  - patients with chronic endocarditis
  - patients requiring pulmonic or tricuspid valve replacement
  - children, adolescents, or young adults

- MRI Safety Information:

  Non-clinical testing has demonstrated that the SJM Biocor® valve is MR safe under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient of 325 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning.

The SJM Biocor® valve produced a temperature rise of ≤ 0.5°C under the conditions listed above. It can be scanned safely under the conditions listed above. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the bioprosthesis.

- Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked or deformed sizers.
- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline used to irrigate the valve.
- Do not add antibiotics to either the valve storage solution or the rinse solution. Do not apply antibiotics to the valve.
- Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Do not expose the valve to extreme temperatures. Freezing or prolonged exposure to heat (45° C and above) may irreversibly damage the biological tissue. Valves that have been exposed to these temperature extremes, or that are suspected of being exposed to these temperature extremes, should not be used. Check the freeze and heat indicators supplied with the valve. If either indicator has turned red, do not use the valve.
- Do not implant the valve without thoroughly rinsing as directed.
- Do not lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced. Do not attempt to repair a valve. Damaged valves must not be used.
- Do not use cutting edge needles, since they may cause structural damage to the bioprosthesis.
- Do not handle the valve with unprotected forceps or sharp instruments. Never handle the leaflet tissue.
- Position the mitral valve in a manner to avoid commissure obstruction of the left ventricular outflow tract, and minimize any potential of commissure contact with the ventricular wall.
- Position the aortic valve so that the stent posts do not obstruct the coronary ostia.
  Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

5. ADVERSE EVENTS

The clinical investigations of the SJM Biocor® valve include data from the two following independent institutions:

Sahlgrenska University Hospital, Gothenburg, Sweden
Between January 1983 and December 1999, 1492 patients requiring aortic and/or mitral valve replacement (AVR = 1263, MVR = 172, DVR = 57) were implanted at the Sahlgrenska University Hospital in Gothenburg, Sweden. The cumulative follow-up for the 1492 total patients in Sweden was 7718.1 patient-years with a mean follow-up of 5.2 years (s.d. = 4.3 years, range 0 – 16.9 years).

University of Padua Medical Center, Padua, Italy
Between May 1992 and December 2000, 442 patients requiring aortic and/or mitral valve replacement (AVR = 262, MVR = 129, DVR = 51) were implanted at the University of Padua Medical Center in Padua, Italy. The cumulative follow-up for the 442 total patients in Italy was 2080.9 patient-years with a mean follow-up of 4.7 years (s.d. = 2.8 years, range 0 – 11.4 years).

5.1 Observed Adverse Events

Tables 2 and 3 present the adverse events for all isolated AVR and MVR patients enrolled at the Sahlgrenska University Hospital, Gothenburg, Sweden. Tables 4 and 5 present the adverse events for all isolated AVR and MVR patients enrolled at the University of Padua Medical Center, Padua, Italy.

Table 2: Observed Adverse Event Rates for AVR (Sweden)
All isolated aortic valve replacements: N=1263, cumulative follow-up=6268.7 late patient-years

Adverse Event	Early Events[1] n=1263		Late Events[2] n=1189		Freedom From Event[3]		
					1 Year	5 Year	8 Year
	n_1	%	n_1	%/pt-yr	% [95% CI]	% [95% CI]	% [95% CI]
Mortality (All)	50	4.11	363	5.79	91.7 [90.1, 93.2]	75.4 [72.7, 78.2]	61.4 [57.9, 65.0]
- Valve-related (includes unknowns)	9	0.87	41	0.66	98.2 [97.5, 99.0]	96.5 [95.3, 97.7]	94.1 [92.2, 96.0]
Reoperation (includes explant)	4	0.48	104	1.86	97.8 [96.4, 99.2]	94.2 [92.1, 96.4]	89.0 [84.5, 93.6]
Explant	4	0.48	104	1.86	97.8 [96.4, 99.2]	94.2 [92.1, 96.4]	89.0 [84.5, 93.6]
Endocarditis	0	0.16	32	0.56	98.9 [97.7, 100.0]	97.3 [95.6, 99.1]	96.0 [93.8, 98.3]
Anticoagulant-related hemorrhage	7	0.71	47	0.80	97.3 [95.7, 98.9]	95.8 [93.9, 97.8]	94.1 [91.6, 96.5]
Nonstructural dysfunction[4]	4	0.48	16	0.26	98.9 [97.7, 100.0]	98.3 [96.9, 99.7]	98.0 [96.5, 99.6]
- Paravalvular leak[5]	4	0.48	16	0.26	98.9 [97.7, 100.0]	98.3 [96.9, 99.7]	98.0 [96.5, 99.6]
Structural deterioration	0	0.16	67	1.12	99.4 [98.9, 99.8]	97.3 [96.2, 98.4]	92.4 [88.2, 96.7]
Embolism (All)	7	0.71	117	1.96	97.0 [95.3, 98.8]	89.6 [85.7, 93.6]	85.1 [80.3, 89.8]
- Permanent	6	0.63	45	0.77	98.7 [97.5, 99.9]	95.5 [92.8, 98.2]	93.4 [90.2, 96.7]
Valve Thrombosis	0	0.16	0	0.00	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]

Table 3: Observed Adverse Event Rates for MVR (Sweden)
All isolated mitral valve replacements: N=172, cumulative follow-up=955.2 late patient-years

Adverse Event	Early Events[1] n=172		Late Events[2] n=152		Freedom From Event[3]		
					1 Year	5 Year	8 Year
	n_1	%	n_1	%/pt-yr	% [95% CI]	% [95% CI]	% [95% CI]
Mortality (All)	19	12.07	66	7.31	80.5 [74.5, 86.5]	63.6 [55.9, 71.3]	47.4 [28.5, 66.3]
- Valve-related (includes unknowns)	2	2.30	10	1.42	96.8 [93.9, 99.6]	94.9 [91.1, 98.7]	88.0 [72.8, 100.0]
Reoperation (includes explant)	0	1.15	21	2.55	97.3 [94.6, 99.9]	92.7 [88.0, 97.4]	86.9 [79.9, 93.9]
Explant	0	1.15	21	2.55	97.3 [94.6, 99.9]	92.7 [88.0, 97.4]	86.9 [79.9, 93.9]
Endocarditis	0	1.15	10	1.06	96.5 [93.5, 99.5]	93.7 [89.3, 98.0]	93.7 [89.3, 98.0]
Anticoagulant-related hemorrhage	0	1.15	10	1.44	94.8 [86.6, 100.0]	92.5 [82.7, 100.0]	90.9 [80.1, 100.0]
Nonstructural dysfunction[4]	0	1.15	3	0.32	99.3 [98.0, 100.0]	97.3 [94.3, 100.0]	97.3 [94.3, 100.0]
- Paravalvular leak[5]	0	1.15	3	0.32	99.3 [98.0, 100.0]	97.3 [94.3, 100.0]	97.3 [94.3, 100.0]
Structural deterioration	0	1.15	10	1.05	100.0 [100.0, 100.0]	99.1 [97.3, 100.0]	94.5 [89.2, 99.9]
Embolism (All)	2	2.30	24	2.52	92.7 [88.5, 96.9]	87.1 [81.2, 93.0]	82.6 [75.2, 90.1]
- Permanent	2	2.30	9	0.95	97.5 [95.0, 99.9]	94.7 [90.7, 98.6]	93.3 [88.5, 98.0]
Valve Thrombosis	0	1.15	0	0.01	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]

1. Early events are those occurring on or before 30 days post-implant (n= number of patients in the subgroup, n_1 = number of patients experiencing the adverse event on or before 30 days post-implant). Adjusted early adverse event rate (%) based on a Bayesian "missing data approach" with rates distributed a priori as Beta (1,1).
2. Late events are those occurring 31 days post-implant or thereafter (n= number of patients in the subgroup, n_1 = number of events that occurred 31 days or more post-implant). Adjusted late rate (%/pt-yr) based on a Bayesian "missing data approach" with rates distributed a priori as Gamma (0.01, 0.01).
3. The survival analyses adjusted estimates (i.e., Freedom from Event) are based on the Bonferroni inequality. The 95% CI = estimate ± 1.96* standard error. The standard error is calculated from the Greenwood standard error for each rate and conservatively assumes the highest possible covariance between the two estimates.
4 Including paravalvular leak.
5 No events related to endocarditis.

Table 4: Observed Adverse Event Rates for AVR (Italy)

All isolated aortic valve replacements: N=262, cumulative follow-up=1309.2 late patient-years

Adverse Event	Early Events[6] n=262		Late Events[7] n=251		Freedom From Event[8]		
					1 Year	5 Year	8 Year
	n_1	%	n_1	%/pt-yr	% [95% CI]	% [95% CI]	% [95% CI]
Mortality (All)	11	4.20	90	6.87	91.5 [88.2, 94.9]	72.0 [66.5, 77.6]	50.8 [42.6, 59.0]
- Valve-related (includes unknowns)	1	0.38	29	2.22	98.4 [96.8, 100.0]	91.2 [87.4, 95.0]	80.8 [73.7, 87.9]
Reoperation (includes explant)	1	0.38	5	0.38	98.4 [96.8, 100.0]	98.4 [96.8, 100.0]	96.8 [94.2, 99.5]
Explant	1	0.38	5	0.38	98.4 [96.8, 100.0]	98.4 [96.8, 100.0]	96.8 [94.2, 99.5]
Endocarditis	0	0.00	3	0.23	99.6 [98.8, 100.0]	98.5 [96.8, 100.0]	98.5 [96.8, 100.0]
Hemolysis	0	0.00	0	0.00	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]
Anticoagulant-related hemorrhage	6	2.29	6	0.46	97.2 [95.2, 99.3]	96.3 [93.9, 98.7]	94.1 [90.3, 97.9]
Nonstructural dysfunction[9]	0	0.00	6	0.46	98.8 [97.4, 100.0]	98.3 [96.7, 100.0]	97.6 [95.5, 99.7]
- Paravalvular leak[10]	0	0.00	6	0.46	98.8 [97.4, 100.0]	98.3 [96.7, 100.0]	97.6 [95.5, 99.7]
Structural deterioration	0	0.00	2	0.15	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	96.8 [91.9, 100.0]
Embolism (All)	2	0.76	17	1.30	96.7 [94.5, 99.0]	92.6 [89.0, 96.1]	91.5 [87.4, 95.6]
- Permanent	0	0.00	9	0.69	98.7 [97.3, 100.0]	96.7 [94.3, 99.1]	95.6 [92.5, 98.8]
Valve Thrombosis	1	0.38	2	0.15	99.2 [98.1, 100.0]	98.7 [97.3, 100.0]	98.7 [97.3, 100.0]

Table 5: Observed Adverse Event Rates for MVR (Italy)

All isolated mitral valve replacements: N=129, cumulative follow-up=499.4 late patient-years

Adverse Event	Early Events[6] n=129		Late Events[7] n=114		Freedom From Event[8]		
					1 Year	5 Year	8 Year
	n_1	%	n_1	%/pt-yr	% [95% CI]	% [95% CI]	% [95% CI]
Mortality (All)	15	11.63	39	7.81	78.2 [71.0, 85.3]	62.5 [53.5, 71.4]	48.1 [35.9, 60.4]
- Valve-related (includes unknowns)	1	0.78	15	3.00	94.4 [90.1, 98.8]	86.5 [79.1, 93.9]	80.9 [71.7, 90.2]
Reoperation (includes explant)	0	0.00	6	1.20	98.2 [95.7, 100.0]	94.1 [89.5, 98.7]	94.1 [89.5, 98.7]
Explant	0	0.00	6	1.20	98.2 [95.7, 100.0]	94.1 [89.5, 98.7]	94.1 [89.5, 98.7]
Endocarditis	1	0.78	5	1.00	96.4 [92.9, 99.9]	95.3 [91.3, 99.4]	91.9 [84.3, 99.5]
Hemolysis	0	0.00	0	0.00	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]
Anticoagulant-related hemorrhage	8	6.20	5	1.00	92.4 [87.6, 97.2]	91.2 [85.9, 96.5]	84.9 [75.0, 94.8]
Nonstructural dysfunction[9]	0	0.00	9	1.80	98.1 [95.5, 100.0]	93.1 [88.1, 98.0]	86.5 [76.1, 96.8]
- Paravalvular leak[10]	0	0.00	9	1.80	98.1 [95.5, 100.0]	93.1 [88.1, 98.0]	86.5 [76.1, 96.8]
Structural deterioration	0	0.00	0	0.00	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]
Embolism (All)	2	1.55	7	1.40	96.5 [93.2, 99.9]	91.1 [85.0, 97.3]	88.6 [80.9, 96.3]
- Permanent	1	0.78	4	0.80	98.3 [95.9, 100.0]	94.3 [89.1, 99.4]	94.3 [89.1, 99.4]
Valve Thrombosis	0	0.00	0	0.00	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]

6. Early events are those occurring on or before 30 days post-implant (n= number of patients in the subgroup, n_1 = number of patients experiencing the adverse event on or before 30 days post-implant). Early adverse event rate (%) = $(n_1/n)*100$.
7. Late events are those occurring 31 days post-implant or thereafter (n= number of patients in the subgroup, n_1 = number of events that occurred 31 days or more post-implant). Late adverse event rate (%/pt-yr) = (n_1/total late patient-years at risk for the event)*100.
8. Survival analyses (i.e., Freedom from Event) were performed using the Kaplan-Meier product limit method. The 95% CI = estimate ± 1.96* standard error (Greenwood formula).

9 Including paravalvular leak.

10 No events related to endocarditis.

5.2 Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include:

- angina
- cardiac arrhythmias
- endocarditis
- heart failure
- hemolysis
- hemolytic anemia
- hemorrhage
- leak, transvalvular or paravalvular
- myocardial infarction
- nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- prosthesis regurgitation
- stroke
- structural deterioration (calcification, leaflet tear, or other)
- thromboembolism
- valve thrombosis

It is possible that these complications could lead to:

- reoperation
- explantation
- permanent disability
- death

6. CLINICAL STUDIES

The clinical investigations of the SJM Biocor® valve include data from the two following independent institutions:

1. Sahlgrenska University Hospital, Gothenburg, Sweden
2. University of Padua Medical Center, Padua, Italy

Sahlgrenska University Hospital, Gothenburg, Sweden

At the Sahlgrenska University Hospital, data were collected from patients implanted with the SJM Biocor® valve between January 1983 and December 1999. This study was a single-center, non-randomized, observational study without concurrent or matched controls. The study included 1492 consecutively implanted patients (AVR = 1263, MVR = 172, DVR = 57). Demographic and baseline data were collected preoperatively. Adverse event data were collected at time of occurrence or upon site notification using definitions from Edmunds *et al.* 1996.

The mean age at implant for the 1492 total patients was 69.4 years (s.d. = 11.8 years, range 16.8 – 88.7 years). Preoperatively, 59.0% of the total patients were NYHA classification III and 11.9% were classification IV. The cumulative follow-up for the total patients in Sweden was 7718.1 patient-years with a mean follow-up of 5.2 years (s.d. = 4.3 years, range 0 to 16.9 years).

University of Padua Medical Center, Padua, Italy

At the University of Padua Medical Center, data were collected from patients implanted with the SJM Biocor® valve between May 1992 and December 2000. This study was a single-center, non-randomized, observational study without concurrent or matched controls. The study included 442 consecutively implanted patients (AVR = 262, MVR = 129, DVR = 51). Demographic and baseline data were collected preoperatively. Adverse event data were collected at time of occurrence or upon site notification using definitions from Edmunds *et al.* 1996.

The mean age at implant for the 442 total patients was 73.7 years (s.d. = 6.2 years, range 45.3 – 90.9 years). Preoperatively, 40.7% of the patients were NYHA classification III and 23.5% were classification IV. The cumulative follow-up for the total patients in Italy was 2080.9 patient-years with a mean follow-up of 4.7 years (s.d. = 2.8 years, range 0 – 11.4 years).

Follow-Up

Tables 6 and 7 present the numbers of patients implanted, cumulative follow-up, and mean follow-up for each patient implant group in Sweden and Italy. Tables 8 and 9 present the numbers of patients implanted and cumulative follow-up by valve size and patient implant group in Sweden and Italy.

Table 6: Patient Numbers, and Cumulative and Mean Follow-up (Sahlgrenska University Hospital, Sweden)
All patients entered into study, N=1492
Mean, SD, Min, and Max are represented in "Years"

Patient Implant Group	Number of Patients	Number of Patient-years	Mean	SD	Min	Max
Isolated Aortic Patients	1263*	6368.6	5.0	4.1	0.0	16.9
Isolated Mitral Patients	172	968.3	5.6	4.9	0.0	16.6
Double Valve Patients	57	381.2	6.7	5.3	0.0	14.6
All Patients	1492	7718.1	5.2	4.3	0.0	16.9

Table 7: Patient Numbers, and Cumulative and Mean Follow-up (University of Padua Medical Center, Italy)
All patients entered into study, N=442
Mean, SD, Min, and Max are represented in "Years"

Patient Implant Group	Number of Patients	Number of Patient-years	Mean	SD	Min	Max
Isolated Aortic Patients	262	1330.0	5.1	2.5	0.0	11.4
Isolated Mitral Patients	129	509.1	3.9	3.0	0.0	11.2
Double Valve Patients	51	241.7	4.7	2.9	0.1	9.6
All Patients	442	2080.9	4.7	2.8	0.0	11.4

Table 8: Aortic Patient Numbers and Cumulative Follow-up by Valve Size

	Valve Size					
	21mm	23mm	25mm	27mm	29mm	Total
Sahlgrenska University Hospital, Sweden						
Number of Isolated Aortic Patients	83	524	407	186	47	1247†
Number of Patient-Years	661.4	2189.2	2110.2	1038.3	267.0	6266.0
University of Padua Medical Center, Italy						
Number of Isolated Aortic Patients	48	116	76	20	2	262
Number of Patient-Years	242.3	586.6	396.8	99.4	4.9	1330.0

Table 9: Mitral Patient Numbers and Cumulative Follow-up by Valve Size

	Valve Size					
	25mm	27mm	29mm	31mm	33mm	Total
Sahlgrenska University Hospital, Sweden						
Number of Isolated Mitral Patients	3	17	45	52	55	172
Number of Patient-Years	35.9	105.2	223.5	296.0	307.8	968.3
University of Padua Medical Center, Italy						
Number of Isolated Mitral Patients	0	4	56	56	13	129
Number of Patient-Years	0.0	14.5	188.8	249.1	56.8	509.1

* Data includes aortic valve sizes 21mm, 23mm, 25mm, 27mm, 29mm, 31mm, and 33mm.

† Data excludes aortic valve sizes 31mm and 33mm.

Preoperative Patient Demographics

Tables 10 and 11 present preoperative patient demographics.

Table 10: Preoperative Patient Demographics (Sahlgrenska University Hospital, Sweden)
All patients entered into study, N=1492; n=number per subgroup

Patient Characteristics		Isolated AVR n=1263		Isolated MVR n=172	
		n_1	% (n_1/n)	n_1	% (n_1/n)
Gender	Male	806	63.8	82	47.7
	Female	457	36.2	90	52.3
Age at Implant	≤39	49	3.9	11	6.4
	40-49	42	3.3	9	5.2
	50-59	83	6.6	27	15.7
	60-69	222	17.6	51	29.7
	70-79	724	57.3	70	40.7
	≥80	143	11.3	4	2.3
NYHA Classification	I	89	7.0	1	0.6
	II	301	23.8	16	9.3
	III	732	58.0	116	67.4
	IV	123	9.7	39	22.7
	Unknown	18	1.4	0	0.0
Valve Dysfunction	Insufficiency	169	13.4	116	67.4
	Stenosis	905	71.7	30	17.4
	Mixed	189	15.0	26	15.1
	Unknown	0	0.0	0	0.0

Table 11: Preoperative Patient Demographics (University of Padua Medical Center, Italy)
All patients entered into study, N=442; n=number per subgroup

Patient Characteristics		Isolated AVR n=262		Isolated MVR n=129	
		n_1	% (n_1/n)	n_1	% (n_1/n)
Gender	Male	128	48.9	41	31.8
	Female	134	51.1	88	68.2
Age at Implant	≤39	0	0.0	0	0.0
	40-49	2	0.8	0	0.0
	50-59	5	1.9	6	4.7
	60-69	33	12.6	30	23.3
	70-79	175	66.8	89	69.0
	≥80	47	17.9	4	3.1
NYHA Classification	I	26	9.9	3	2.3
	II	88	33.6	26	20.2
	III	95	36.3	66	51.2
	IV	53	20.2	32	24.8
	Unknown	0	0.0	2	1.6
Valve Dysfunction	Insufficiency	33	12.6	82	63.6
	Stenosis	178	67.9	15	11.6
	Mixed	50	19.1	32	24.8
	Unknown	1	0.4	0	0.0

Effectiveness Outcomes

Quantitative data were collected throughout the study (i.e., NYHA functional classification, echo parameters). Table 12 presents patient NYHA classification at two time points: preoperative and ≥ 11 months follow-up for both Sweden and Italy. Tables 13 and 14 present hemodynamic results at ≥ 11 months follow-up for both Sweden and Italy.

Table 12: Effectiveness Outcomes, NYHA Functional Classification: ≥ 11 Months Follow-up

Sahlgrenska University Hospital, Sweden All patients entered into study, N=1492; n=number per subgroup								
NYHA Class	**Isolated AVR**				**Isolated MVR**			
	Preoperative Assessment n = 949		Postoperative ≥ 11 months n = 949		Preoperative Assessment n = 116		Postoperative ≥ 11 months n = 116	
	n_1	% (n_1/n)	n_1	% (n_1/n)	n_1	% (n_1/n)	n_1	% (n_1/n)
I	59	6.2	528	55.6	0	0.0	57	49.1
II	242	25.5	310	32.7	12	10.3	44	37.9
III	557	58.7	108	11.4	84	72.4	14	12.1
IV	91	9.6	3	0.3	20	17.2	1	0.9
University of Padua Medical Center, Italy All patients entered into study, N=442; n=number per subgroup								
NYHA Class	**Isolated AVR**				**Isolated MVR**			
	Preoperative Assessment n = 215		Postoperative ≥ 11 months n = 215		Preoperative Assessment n = 89		Postoperative ≥ 11 months n = 89	
	n_1	% (n_1/n)	n_1	% (n_1/n)	n_1	% (n_1/n)	n_1	% (n_1/n)
I	23	10.7	122	56.7	3	3.4	38	42.7
II	77	35.8	76	35.3	22	24.7	37	41.6
III	72	33.5	14	6.5	52	58.4	9	10.1
IV	43	20.0	3	1.4	12	13.5	5	5.6

Table 13: Effectiveness Outcomes, Aortic Hemodynamic Results

Sahlgrenska University Hospital, Sweden All Aortic Valve Replacements, N=1320										
Hemodynamic Parameter	Results by Valve Size									
	21mm		23mm		25mm		27mm		29mm	
Data from the Follow-up interval ≥ 11 months										
Mean Gradient (mmHg)	N=63		N=170		N=205		N=104		N=28	
Mean ± SD	22.4 ± 7.4		18.9 ± 9.9		17.9 ± 11.4		16.4 ± 11.5		17.2 ± 11.2	
EOA (cm^2)	N=15		N=37		N=31		N=19		N=2	
♦ Mean ± SD	1.0 ± 0.3		1.3 ± 0.5		1.4 ± 0.5		1.9 ± 0.7		1.7 ± 0.4	
Regurgitation	21mm		23mm		25mm		27mm		29mm	
	n	%	n	%	n	%	n	%	n	%
♦ None	37	58.7	111	60.0	104	48.4	60	56.6	13	40.6
♦ Trivial	18	28.6	45	24.3	56	26.1	26	24.5	10	31.3
♦ Mild	6	9.5	16	8.7	29	13.5	14	13.2	3	9.4
♦ Moderate	1	1.6	12	6.5	19	8.8	4	3.8	6	18.8
♦ Severe	1	1.6	1	0.5	7	3.3	2	1.9	0	0.0

University of Padua Medical Center, Italy All Aortic Valve Replacements, N=313										
Hemodynamic Parameter	Results by Valve Size									
	21mm		23mm		25mm		27mm		29mm	
Data from the Follow-up interval ≥ 11 months										
Mean Gradient (mmHg)	N=40		N=93		N=61		N=12		N=1	
Mean ± SD	18.8 ± 6.3		17.3 ± 7.6		15.2 ± 5.2		13.9 ± 4.8		11.00 ± NA	
EOA (cm^2)	N=36		N=88		N=59		N=9		N=1	
♦ Mean ± SD	1.3 ± 0.3		1.5 ± 0.3		1.5 ± 0.3		1.5 ± 0.2		3.3 ± NA	
Regurgitation	21mm		23mm		25mm		27mm		29mm	
	n	%	n	%	n	%	n	%	n	%
♦ None	34	79.1	84	90.3	56	91.8	10	83.3	1	100
♦ Trivial	7	16.3	8	8.6	4	6.6	2	16.7	0	0.0
♦ Mild	2	4.7	1	1.1	0	0.0	0	0.0	0	0.0
♦ Moderate	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0
♦ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 14: Effectiveness Outcomes, Mitral Hemodynamic Results

Sahlgrenska University Hospital, Sweden All Mitral Valve Replacements, N=229										
Hemodynamic Parameter	Results by Valve Size									
	25mm		27mm		29mm		31mm		33mm	
Data from the Follow-up interval ≥ 11 months										
Mean Gradient (mmHg)	N=2		N=6		N=23		N=29		N=26	
Mean ± SD	6.5 ± 2.1		7.5 ± 2.7		6.6 ± 2.3		5.2 ± 1.9		7.2 ± 3.9	
EOA (cm^2)	N=1		N=0		N=2		N=4		N=3	
♦ Mean ± SD	0.9 ± N/A		N/A		1.5 ± 0.1		1.7 ± 0.8		1.8 ± 1.1	
Regurgitation	25mm		27mm		29mm		31mm		33mm	
	n	%	n	%	n	%	n	%	n	%
♦ None	0	0.0	4	50.0	18	58.1	23	60.5	27	64.3
♦ Trivial	2	66.7	1	12.5	9	29.0	7	18.4	6	14.3
♦ Mild	1	33.3	0	0.0	3	9.7	5	13.2	4	9.5
♦ Moderate	0	0.0	2	25.0	0	0.0	1	2.6	3	7.1
♦ Severe	0	0.0	1	12.5	1	3.2	2	5.3	2	4.8

University of Padua Medical Center, Italy All Mitral Valve Replacements, N=180										
Hemodynamic Parameter	Results by Valve Size									
	25mm		27mm		29mm		31mm		33mm	
Data from the Follow-up interval ≥ 11 months										
Mean Gradient (mmHg)	N=0		N=3		N=43		N=39		N=11	
Mean ± SD	N/A		6.1 ± 1.3		6.3 ± 3.1		5.9 ± 3.1		6.5 ± 3.8	
EOA (cm^2)	N=0		N=2		N=40		N=25		N=11	
♦ Mean ± SD	N/A		1.2 ± 0.3		2.3 ± 0.6		2.2 ± 0.6		2.3 ± 0.7	
Regurgitation	25mm		27mm		29mm		31mm		33mm	
	n	%	n	%	n	%	n	%	n	%
♦ None	0	0.0	3	100	34	79.1	29	74.4	9	75.0
♦ Trivial	0	0.0	0	0.0	8	18.6	5	12.8	3	25.0
♦ Mild	0	0.0	0	0.0	1	2.3	5	12.8	0	0.0
♦ Moderate	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
♦ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Hemodynamic data was also obtained from another foreign institution to augment the 27mm mitral data from Sweden and Italy. Hemodynamic data was collected from the Biocor Hospital de Doencas Cardiovaculares Ltda., Brazil (Biocor Hospital). The hemodynamic results at ≥ 11 months follow-up from the Biocor Hospital are presented in Table 15.

Table 15: Effectiveness Outcomes, 27mm Mitral Hemodynamic Results

Biocor Hospital de Doencas Cardiovaculares Ltda, Brazil All 27mm Mitral Valve Replacements, N=228		
Hemodynamic Parameter	27mm Mitral Valve	
Data from the Follow-up interval ≥ 11 months		
Mean Gradient (mmHg)	N=30	
Mean ± SD	7.3 ± 3.7	
EOA (cm^2)	N=13	
♦ Mean ± SD	1.5 ± 0.3	
Regurgitation	27mm Mitral Valve	
	n	%
♦ None	24	70.6
♦ Trivial	3	8.8
♦ Mild	6	17.7
♦ Moderate	0	0.0
♦ Severe	1	2.9

7. INDIVIDUALIZATION OF TREATMENT

7.1 Anticoagulant and/or Antiplatelet Therapy

Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

8. PATIENT COUNSELING INFORMATION

Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

Patients with bioprostheses who undergo dental or other procedures which are potentially bacteremic should receive endocarditis prophylactic antibiotic therapy.

Patients should be encouraged to complete the patient identification card provided with the valve and to carry it with them at all times.

St. Jude Medical publishes a patient brochure, "SJM Biocor® Valve / SJM Biocor® Supra Valve Patient Education Booklet," that may be available to the patient. Copies of this booklet are available through your SJM sales representative. A copy should be provided to each patient.

9. PACKAGING AND STORAGE

As delivered, the valve is attached to a valve holder by three retaining sutures. A flexible plastic support surrounds the valve. The valve holder and support facilitate handling and manipulation of the valve during removal from the container, rinsing, and implantation.

The valve is packaged in a formaldehyde storage solution. Store the valve in the upright position.

CAUTION: Do not implant the valve without thoroughly rinsing as directed.

Storage Temperature Indicator
The valve should be stored in temperatures from 5° to 25° C (41° to 77° F). Do not store the valve where significant temperature fluctuations may occur. If the valve has been exposed to extreme temperatures, the freeze indicator or heat indicator will turn red. If either indicator has turned red, do not use the valve.

CAUTION: Do not expose valves to extreme temperatures. Freezing or prolonged exposure to heat (45° C and above) may irreversibly damage the biological tissue. Valves that have been exposed to these temperature extremes, or that are suspected of being exposed to these temperature extremes, should not be used.

Sizers
Use only the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Models B805 or B807 with the SJM Biocor® valve. See the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Model B805 or B807 Physician's Manual for specific instructions on cleaning, sterilization, and handling.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked or deformed sizers.

10. DIRECTIONS FOR USE

10.1 Pre-Implant Handling
The SJM Biocor® valve is supplied in a storage container with a screw-cap closure and tamper-evident seal. The contents of the container are sterile, and must be handled aseptically to prevent contamination.

WARNING: Do not use the valve if the expiration date has elapsed.

WARNING: Do not use the valve if fluid is leaking from the packaging.

WARNING: Do not resterilize the valve by any method.

10.2 Removing the valve from the outer packaging

PRECAUTIONS:
- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline used to irrigate the valve.
- Do not add antibiotics to either the valve storage solution or the rinse solution.
- Do not apply antibiotics to the valve.

1. After sizing, choose a valve of the appropriate size.
2. Once the valve container has been removed from the outer packaging, examine the container for evidence of damage.

WARNING: The valve must not be implanted if the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging.
WARNING: The valve must not be implanted if the storage solution does not completely cover the valve.

3. Verify the valve size and expiration date on the label.

4. To remove the valve from the container, break the seal and remove the screw-top closure.

Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

10.3 Removing the valve from the storage container

1. With the circulating nurse holding the container, screw the valve holder handle into the valve holder as shown in Figure 2, and remove the valve from the jar.

Figure 2 - Remove the valve using the valve holder handle.

CAUTION: Do not handle the valve with unprotected forceps or sharp instruments. Never handle the leaflet tissue.

2. Inspect the valve for damage.

WARNING: Do not implant the valve if the valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration.

10.4 Rinse procedure

CAUTION: Do not implant the valve without thoroughly rinsing as directed.

1. Within the sterile field prepare three sterile basins with a minimum of 500 ml of sterile isotonic saline in each basin.
2. Holding the valve by the handle, **fully immerse** the valve support, the valve, the valve holder, and the portion of the holder handle that was submerged in the valve storage solution, in the sterile isotonic saline solution in the first basin.
3. Continually rinse the valve for two minutes, using a gentle back-and-forth motion.
4. Repeat step three in each of the remaining two basins.
5. After rinsing, leave the valve immersed in the third basin until required by the surgeon for implantation.
6. Prior to implantation, remove the valve support by depressing the three tabs below the level of the valve support ring, as indicated Figure 3.

Figure 3 - To release the valve support from the valve cuff, depress the three tabs at the base of the valve support below the support ring.

CAUTION: Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution.

10.5 Surgical Guidelines

The actual choice of surgical technique, modified in accordance with the instructions described herein, is left to the discretion of the individual surgeon.

10.6 Sizing

The diameter of a given sizer corresponds to the portion of the stent that is placed intra-annularly. The sizer that fits snugly in the annulus is the sizer that identifies the valve that should be selected. While the stent portion of the bioprosthesis fits intra-annularly, the cuff of the bioprosthesis is designed for supra-annular placement.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked or deformed sizers.

WARNING: Valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Model B805 or B807 sizers for sizing of SJM Biocor® valves.

NOTE: The sizer posts may be used to approximate placement of an aortic valve in a manner such that the coronary ostia are not obstructed.

10.7 Aortic Valve Implantation

1. Select a valve based on a sizer that fits snugly in the annulus.
2. Avoid any contact between the implantation sutures and the leaflets.

PRECAUTIONS:

- Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Position the valve so that the stent posts do not obstruct the coronary ostia.
- Do not lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced. Do not attempt to repair a valve. Damaged valves must not be used.
- Do not use cutting edge needles, since they may cause structural damage to the bioprosthesis.

3. To remove the holder from the valve, cut the three retaining sutures as shown in Figure 4, and pull the handle and the valve holder away from the valve. After removing the holder, examine the valve to ensure that there are no holder suture remnants.

Figure 4 - Aortic holder removal.

10.8 Mitral Valve Implantation

1. Select a valve based on a sizer that fits snugly in the annulus.
2. Select a valve that can be accommodated by the size and configuration of the ventricle and the tissue annulus.

PRECAUTIONS:

- Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Position the mitral valve in a manner to avoid commissure obstruction of the left ventricular outflow tract, and minimize any potential of commissure contact with the ventricular wall.
- Do not lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced. Do not attempt to repair a valve. Damaged valves must not be used.
- Do not use cutting edge needles, since they may cause structural damage to the bioprosthesis.

3. To facilitate insertion of the mitral valve into the annulus, the mitral valve stent posts may be temporarily deflected inward during implantation. To deflect the valve stent posts inward, rotate the thumb screw on the valve holder handle in the clockwise direction.

NOTE: Take care to avoid looping or entangling a suture around the commissural post, which may result in a compromise of leaflet function.

4. Avoid any contact between the implant sutures and the leaflets.
5. To remove the holder from the valve, cut the three retaining sutures as shown in Figure 5, and pull the handle and the valve holder away from the valve. After removing the holder, examine the valve to ensure that there are no holder suture remnants.

Figure 5 - Mitral holder removal.

10.9 Intra-Operative Assessment

The suggested method for assessing competence of the SJM Biocor® valve is with intra-operative Doppler echocardiography.

11. PATIENT REGISTRATION

A Medical Device Registration form is included with each device. After implantation, please complete all requested information, and return the original form to the address indicated on the Medical Device Registration form. Tracking by manufacturers is mandatory within the United States. For countries outside of the United States please disregard any request for patient information if this contradicts your local legal or regulatory requirements regarding patient privacy.

12. LIMITED WARRANTY

St. Jude Medical (SJM) warrants that reasonable care has been used in the manufacturing of this device. THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, since handling, storage, cleaning, and sterilization of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond SJM's control directly affect this device and the results obtained from its use. SJM SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE directly or indirectly arising from the use of this device other than the replacement of all or part of it. SJM neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Some states in the United States do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you. This limited warranty gives you specific legal rights, and you may have other rights which vary from jurisdiction to jurisdiction.

Descriptions of specifications, appearing in SJM literature, are meant solely to generally describe the device at the time of manufacture and do not constitute any express warranties.

Corporate Headquarters:
St. Jude Medical, Inc.
One Lillehei Plaza
St. Paul, Minnesota 55117 USA

Manufactured by:
St. Jude Medical Brasil Ltda.
Rua da Paisagem, 310B
Vila da Serra
Nova Lima- MG
CEP 34.000-000 Brazil

24-hour Technical Professional Consultation

Telephone: (800) 328-9634-U.S.A. Toll Free
(651) 483-2000
Fax: (651) 482-8318

Customer Service:

Telephone: (800) 544-1664-U.S.A. Toll Free
(651) 490-4410
Fax: (651) 481-7702

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St. Jude Medical Physician's Manual
SJM Biocor® Supra Valve

(Symbols)
Serial Number
Use Before Date
Model Number
Single Use Only
Processed Using Aseptic Technique
Long Term Storage/Do Not Refrigerate
Mfg. Date
Consult Instructions for Use
Manufacturer
Authorized European Representative

Table of Contents

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

1. DEVICE DESCRIPTION

The SJM Biocor® Supra valve, Figure 1, is a triple-composite bioprosthetic heart valve manufactured from select porcine aortic valve cusps. The cusps are carefully matched for optimum leaflet coaptation and hemodynamics. Only cusps devoid of the septal muscle bar are utilized in the fabrication of the valve. The SJM Biocor® Supra valve is designed for supra-annular placement in the aortic position.

Following tissue fixation, the tissue is mounted on a polyester-covered flexible acetal copolymer stent. The valve sewing cuff contains a silicone elastomer insert. For radiopaque visualization, the SJM Biocor® Supra valve contains a wire within the sewing cuff.

The SJM Biocor® Supra valve is fabricated with a bovine pericardial sheath. The pericardial sheath is attached directly to the outflow edge of the valve thereby protecting the leaflets as they open and close. The pericardial sheath and the porcine valve cusps are preserved and crosslinked in a glutaraldehyde solution. Glutaraldehyde, formaldehyde and ethanol are used in the valve sterilization process. The SJM Biocor® Supra valve is supplied sterile and non-pyrogenic. See Table 1 for model number descriptions and reference dimensions:

Table 1: Model Number Descriptions and Reference Dimensions

Model Number	Tissue Annulus Diameter (mm)	Aortic/Ventricular Protrusion (mm)	Total Height (mm)
B10SP-19	19	11	14
B10SP-21	21	11	15
B10SP-23	23	13	16

Figure 1 - Aortic Valve

2. INDICATIONS FOR USE

The SJM Biocor® Supra valve is intended as a replacement for a diseased, damaged, or malformed native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

3. CONTRAINDICATIONS

None known.

4. WARNINGS AND PRECAUTIONS

4.1 Warnings

- Valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Model B807 sizers for sizing of SJM Biocor® Supra valves.
- Accelerated deterioration due to calcific degeneration of the SJM Biocor® Supra valve may occur in:
  - Children, adolescents, or young adults
  - Patients with altered calcium metabolism (e.g., patients with hyperparathyroidism or chronic renal failure)
  - Individuals requiring hemodialysis
- For single use only.
- Do not resterilize the valve by any method.
- Passage of a catheter or transvenous pacing lead through any bioprosthesis may damage the valve and is therefore not recommended.

S1

Do not use if:

- The valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration;
- The expiration date has elapsed;
- The tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging; or
- The storage solution does not completely cover the valve.

4.2 Precautions

- Safety and effectiveness of the SJM Biocor® Supra valve have not been established for the following specific populations:
  - patients who are pregnant
  - nursing mothers
  - patients with chronic renal failure
  - patients with aneurysmal aortic degenerative conditions, e.g., cystic medial necrosis, Marfan's syndrome
  - patients with chronic endocarditis
  - patients requiring pulmonic or tricuspid valve replacement
  - children, adolescents, or young adults

- MRI Safety:

  Non-clinical testing has demonstrated that the SJM Biocor® valve is MR safe under the following conditions:
  - Static magnetic field of 3 Tesla or less
  - Spatial gradient of 325 Gauss/cm or less
  - Maximum whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning.

  The SJM Biocor® valve produced a temperature rise of $\leq 0.5^{\circ}C$ under the conditions listed above. It can be scanned safely under the conditions listed above. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the bioprosthesis.

- Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked or deformed sizers.
- Do not pass the flanged portion of the sizer through the annulus when sizing the valve.
- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline used to irrigate the valve.
- Do not add antibiotics to either the valve storage solution or the rinse solution. Do not apply antibiotics to the valve.
- Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Do not expose the valve to extreme temperatures. Freezing or prolonged exposure to heat (45° C and above) may irreversibly damage the biological tissue. Valves that have been exposed to these temperature extremes, or that are suspected of being exposed to these temperature extremes, should not be used. Check the freeze and heat indicators supplied with the valve. If either indicator has turned red, do not use the valve.
- Do not implant the valve without thoroughly rinsing as directed.
- Do not lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced. Do not attempt to repair a valve. Damaged valves must not be used.
- Do not use cutting edge needles, since they may cause structural damage to the bioprosthesis.
- Do not handle the valve with unprotected forceps or sharp instruments. Never handle the leaflet tissue.
- Position the aortic valve so that the stent posts do not obstruct the coronary ostia.

- Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

5. ADVERSE EVENTS

The clinical investigations of the SJM Biocor® valve support the safety and efficacy of the SJM Biocor® Supra valve and include data from the two following independent institutions:

Sahlgrenska University Hospital, Gothenburg, Sweden
Between January 1983 and December 1999, 1492 patients requiring aortic and/or mitral valve replacement (AVR = 1263, MVR = 172, DVR = 57) were implanted at the Sahlgrenska University Hospital in Gothenburg, Sweden. The cumulative follow-up for the 1492 total patients in Sweden was 7718.1 patient-years with a mean follow-up of 5.2 years (s.d. = 4.3 years, range 0 – 16.9 years).

University of Padua Medical Center, Padua, Italy
Between May 1992 and December 2000, 442 patients requiring aortic and/or mitral valve replacement (AVR = 262, MVR = 129, DVR = 51) were implanted at the University of Padua Medical Center in Padua, Italy. The cumulative follow-up for the 442 total patients in Italy was 2080.9 patient-years with a mean follow-up of 4.7 years (s.d. = 2.8 years, range 0 – 11.4 years).

5.1 Observed Adverse Events

Table 2 presents the adverse events for all isolated AVR patients enrolled at the Sahlgrenska University Hospital, Gothenburg, Sweden. Table 3 presents the adverse events for all isolated AVR patients enrolled at the University of Padua Medical Center, Padua, Italy.

Table 2: Observed Adverse Event Rates for AVR (Sweden)

All isolated aortic valve replacements: N=1263, cumulative follow-up=6268.7 late patient years

Adverse Event	Early Events[1] n=1263		Late Events[2] n=1189		Freedom From Event[3]		
					1 Year	5 Year	8 Year
	n_1	%	n_1	%/pt-yr	% [95% CI]	% [95% CI]	% [95% CI]
Mortality (All)	50	4.11	363	5.79	91.7 [90.1, 93.2]	75.4 [72.7, 78.2]	61.4 [57.9, 65.0]
- Valve-related (includes unknowns)	9	0.87	41	0.66	98.2 [97.5, 99.0]	96.5 [95.3, 97.7]	94.1 [92.2, 96.0]
Reoperation (including explant)	4	0.48	104	1.86	97.8 [96.4, 99.2]	94.2 [92.1, 96.4]	89.0 [84.5, 93.6]
Explant	4	0.48	104	1.86	97.8 [96.4, 99.2]	94.2 [92.1, 96.4]	89.0 [84.5, 93.6]
Endocarditis	0	0.16	32	0.56	98.9 [97.7, 100.0]	97.3 [95.6, 99.1]	96.0 [93.8, 98.3]
Anticoagulant-related hemorrhage	7	0.71	47	0.80	97.3 [95.7, 98.9]	95.8 [93.9, 97.8]	94.1 [91.6, 96.5]
Nonstructural dysfunction[4]	4	0.48	16	0.26	98.9 [97.7, 100.0]	98.3 [96.9, 99.7]	98.0 [96.5, 99.6]
- Paravalvular leak[5]	4	0.48	16	0.26	98.9 [97.7, 100.0]	98.3 [96.9, 99.7]	98.0 [96.5, 99.6]
Structural deterioration	0	0.16	67	1.12	99.4 [98.9, 99.8]	97.3 [96.2, 98.4]	92.4 [88.2, 96.7]
Embolism (All)	7	0.71	117	1.96	97.0 [95.3, 98.8]	89.6 [85.7, 93.6]	85.1 [80.3, 89.8]
- Permanent	6	0.63	45	0.77	98.7 [97.5, 99.9]	95.5 [92.8, 98.2]	93.4 [90.2, 96.7]
Valve Thrombosis	0	0.16	0	0.00	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]

Table 3: Observed Adverse Event Rates for AVR (Italy)

All isolated aortic valve replacements: N=262, cumulative follow-up=1309.2 late patient-years

Adverse Event	Early Events[6] n=262		Late Events[7] n=251		Freedom From Event[8]		
					1 Year	5 Year	8 Year
	n_1	% (n_1/n)	n_1	%/pt-yr	% [95% CI]	% [95% CI]	% [95% CI]
Mortality (All)	11	4.20	90	6.87	91.5 [88.2, 94.9]	72.0 [66.5, 77.6]	50.8 [42.6, 59.0]
- Valve-related (includes unknowns)	1	0.38	29	2.22	98.4 [96.8, 100.0]	91.2 [87.4, 95.0]	80.8 [73.7, 87.9]
Reoperation (includes explant)	1	0.38	5	0.38	98.4 [96.8, 100.0]	98.4 [96.8, 100.0]	96.8 [94.2, 99.5]
Explant	1	0.38	5	0.38	98.4 [96.8, 100.0]	98.4 [96.8, 100.0]	96.8 [94.2, 99.5]
Endocarditis	0	0.00	3	0.23	99.6 [98.8, 100.0]	98.5 [96.8, 100.0]	98.5 [96.8, 100.0]
Hemolysis	0	0.00	0	0.00	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]
Anticoagulant-related hemorrhage	6	2.29	6	0.46	97.2 [95.2, 99.3]	96.3 [93.9, 98.7]	94.1 [90.3, 97.9]
Nonstructural dysfunction[9]	0	0.00	6	0.46	98.8 [97.4, 100.0]	98.3 [96.7, 100.0]	97.6 [95.5, 99.7]
- Paravalvular leak[10]	0	0.00	6	0.46	98.8 [97.4, 100.0]	98.3 [96.7, 100.0]	97.6 [95.5, 99.7]
Structural deterioration	0	0.00	2	0.15	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	96.8 [91.9, 100.0]
Embolism (All)	2	0.76	17	1.30	96.7 [94.5, 99.0]	92.6 [89.0, 96.1]	91.5 [87.4, 95.6]
- Permanent	0	0.00	9	0.69	98.7 [97.3, 100.0]	96.7 [94.3, 99.1]	95.6 [92.5, 98.8]
Valve Thrombosis	1	0.38	2	0.15	99.2 [98.1, 100.0]	98.7 [97.3, 100.0]	98.7 [97.3, 100.0]

1. Early events are those occurring on or before 30 days post-implant (n= number of patients in the subgroup, n_1 = number of patients experiencing the adverse event on or before 30 days post-implant). Adjusted early adverse event rate (%) based on a Bayesian "missing data approach" with rates distributed a priori as Beta (1,1).
2. Late events are those occurring 31 days post-implant or thereafter (n= number of patients in the subgroup, n_1 = number of events that occurred 31 days or more post-implant). Adjusted late rate (%/pt-yr) based on a Bayesian "missing data approach" with rates distributed a priori as Gamma (0.01, 0.01).
3. The survival analyses adjusted estimates (i.e. Freedom from Event) are based on the Bonferroni inequality. The 95% CI = estimate ± 1.96* standard error. The standard error is calculated from the Greenwood standard error for each rate and conservatively assumes the highest possible covariance between the two estimates.
4 Including paravalvular leak.
5 No events related to endocarditis.
6. Early events are those occurring on or before 30 days post-implant (n= number of patients in the subgroup, n_1 = number of patients experiencing the adverse event on or before 30 days post-implant). Early adverse event rate (%) = (n_1/n)*100.
7. Late events are those occurring 31 days post-implant or thereafter (n= number of patients in the subgroup, n_1 = number of events that occurred 31 days or more post-implant). Late adverse event rate (%/pt-yr) = (n_1/total late patient-years at risk for the event)*100.
8. Survival analyses (i.e., Freedom from Event) were performed using the Kaplan-Meier product limit method. The 95% CI = estimate ± 1.96* standard error (Greenwood formula).
9. Including paravalvular leak.
10. No events related to endocarditis.

5.2 Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include:

- angina
- cardiac arrhythmias
- endocarditis
- heart failure
- hemolysis
- hemolytic anemia
- hemorrhage
- leak, transvalvular or paravalvular
- myocardial infarction
- nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- prosthesis regurgitation
- stroke
- structural deterioration (calcification, leaflet tear, or other)
- thromboembolism
- valve thrombosis

It is possible that these complications could lead to:

- reoperation
- explantation
- permanent disability
- death

6. CLINICAL STUDIES

The clinical investigations of the SJM Biocor® valve support the safety and efficacy of the SJM Biocor Supra® valve and include data from the two following independent institutions:

1. Sahlgrenska University Hospital, Gothenburg, Sweden
2. University of Padua Medical Center, Padua, Italy

Sahlgrenska University Hospital, Gothenburg, Sweden

At the Sahlgrenska University Hospital, data were collected from patients implanted with the SJM Biocor® valve between January 1983 and December 1999. This study was a single-center, non-randomized, observational study without concurrent or matched controls. The study included 1492 consecutively implanted patients (AVR = 1263, MVR = 172, DVR = 57). Demographic and baseline data were collected preoperatively. Adverse event data were collected at time of occurrence or upon site notification using definitions from Edmunds *et al.* 1996.

The mean age at implant for the 1492 total patients was 69.4 years (s.d. = 11.8 years, range 16.8 – 88.7 years). Preoperatively, 59.0% of the total patients were NYHA classification III and 11.9% were classification IV. The cumulative follow-up for the total patients in Sweden was 7718.1 patient-years with a mean follow-up of 5.2 years (s.d. = 4.3 years, range 0 to 16.9 years).

University of Padua Medical Center, Padua, Italy

At the University of Padua Medical Center, data were collected from patients implanted with the SJM Biocor® valve between May 1992 and December 2000. This study was a single-center, non-randomized, observational study without concurrent or matched controls. The study included 442 consecutively implanted patients (AVR = 262, MVR = 129, DVR = 51). Demographic and baseline data were collected preoperatively. Adverse event data were collected at time of occurrence or upon site notification using definitions from Edmunds *et al.* 1996.

The mean age at implant for the 442 total patients was 73.7 years (s.d. = 6.2 years, range 45.3 – 90.9 years). Preoperatively, 40.7% of the patients were NYHA classification III and 23.5% were classification IV. The cumulative follow-up for the total patients in Italy was 2080.9 patient-years with a mean follow-up of 4.7 years (s.d. = 2.8 years, range 0 – 11.4 years).

Follow-Up

Tables 4 and 5 present the numbers of patients implanted, cumulative follow-up, and mean follow-up for each patient implant group in Sweden and Italy. Table 6 presents the numbers of patients implanted and cumulative follow-up for aortic implants in Sweden and Italy.

Table 4: Patient Numbers, and Cumulative and Mean Follow-up (Sahlgrenska University Hospital, Sweden)
All patients entered into study, N=1492
Mean, SD, Min and Max are represented in "Years"

Patient Implant Group	Number of Patients	Number of Patient-years	Mean	SD	Min	Max
Isolated Aortic Patients	1263*	6368.6	5.0	4.1	0.0	16.9
Isolated Mitral Patients	172	968.3	5.6	4.9	0.0	16.6
Double Valve Patients	57	381.2	6.7	5.3	0.0	14.6
All Patients	1492	7718.1	5.2	4.3	0.0	16.9

Table 5: Patient Numbers, and Cumulative and Mean Follow-up (University of Padua Medical Center, Italy)
All patients entered into study, N=442
Mean, SD, Min and Max are represented in "Years"

Patient Implant Group	Number of Patients	Number of Patient-years	Mean	SD	Min	Max
Isolated Aortic Patients	262	1330.0	5.1	2.5	0.0	11.4
Isolated Mitral Patients	129	509.1	3.9	3.0	0.0	11.2
Double Valve Patients	51	241.7	4.7	2.9	0.1	9.6
All Patients	442	2080.9	4.7	2.8	0.0	11.4

Table 6: Aortic Patient Numbers and Cumulative Follow-up by Valve Size

	Valve Size					
	21mm	23mm	25mm	27mm	29mm	Total
Sahlgrenska University Hospital, Sweden						
Number of Isolated Aortic Patients	83	524	407	186	47	1247†
Number of Patient-Years	661.4	2189.2	2110.2	1038.3	267.0	6266.0
University of Padua Medical Center, Italy						
Number of Isolated Aortic Patients	48	116	76	20	2	262
Number of Patient-Years	242.3	586.6	396.8	99.4	4.9	1330.0

* Data includes aortic valve sizes 21mm, 23mm, 25mm, 27mm, 29mm, 31mm, and 33mm.

† Data excludes aortic valve sizes 31mm and 33mm.

Preoperative Patient Demographics

Tables 7 and 8 present preoperative patient demographics.

Table 7: Preoperative Patient Demographics (Sahlgrenska University Hospital, Sweden)
All isolated aortic valve replacements: n=1263, n_1=number per subgroup

Patient Characteristics		Isolated AVR n=1263	
		n_1	% (n_1/n)
Gender	Male	806	63.8
	Female	457	36.2
Age at Implant	≤39	49	3.9
	40-49	42	3.3
	50-59	83	6.6
	60-69	222	17.6
	70-79	724	57.3
	≥80	143	11.3
NYHA Classification	I	89	7.0
	II	301	23.8
	III	732	58.0
	IV	123	9.7
	Unknown	18	1.4
Valve Dysfunction	Insufficiency	169	13.4
	Stenosis	905	71.7
	Mixed	189	15.0
	Unknown	0	0.0

Table 8: Preoperative Patient Demographics (University of Padua Medical Center, Italy)
All isolated aortic valve replacements: n=262; n_1=number per subgroup

Patient Characteristics		Isolated AVR n=262	
		n_1	% (n_1/n)
Gender	Male	128	48.9
	Female	134	51.1
Age at Implant	≤39	0	0.0
	40-49	2	0.8
	50-59	5	1.9
	60-69	33	12.6
	70-79	175	66.8
	≥80	47	17.9
NYHA Classification	I	26	9.9
	II	88	33.6
	III	95	36.3
	IV	53	20.2
	Unknown	0	0.0
Valve Dysfunction	Insufficiency	33	12.6
	Stenosis	178	67.9
	Mixed	50	19.1
	Unknown	1	0.4

Effectiveness Outcomes

Quantitative data were collected throughout the study (i.e., NYHA functional classification, echo parameters). Table 9 presents patient NYHA classification at two time points: preoperative and ≥ 11 months follow-up for isolated aortic valve implants for both Sweden and Italy. Table 10 presents hemodynamic results for isolated aortic valve implants at ≥ 11 months follow-up for both Sweden and Italy.

Table 9: Effectiveness Outcomes, NYHA Functional Classification: ≥ 11 Months Follow-up

Sahlgrenska University Hospital, Sweden All isolated aortic valve replacements: n=1263, n_1=number per subgroup				
NYHA Class	**Isolated AVR**			
	Preoperative Assessment n = 949		Postoperative ≥ 11 months n = 949	
	n_1	% (n_1/n)	n_1	% (n_1/n)
I	59	6.2	528	55.6
II	242	25.5	310	32.7
III	557	58.7	108	11.4
IV	91	9.6	3	0.3
University of Padua Medical Center, Italy All isolated aortic valve replacements: n=262; n_1=number per subgroup				
NYHA Class	**Isolated AVR**			
	Preoperative Assessment n = 215		Postoperative ≥ 11 months n = 215	
	n_1	% (n_1/n)	n_1	% (n_1/n)
I	23	10.7	122	56.7
II	77	35.8	76	35.3
III	72	33.5	14	6.5
IV	43	20.0	3	1.4

Table 10: Effectiveness Outcomes, Aortic Hemodynamic Results

Sahlgrenska University Hospital, Sweden All Aortic Valve Replacements, N=1320										
Hemodynamic Parameter	Results by Valve Size									
	21mm		23mm		25mm		27mm		29mm	
Data from the Follow-up interval ≥ 11 months										
Mean Gradient (mmHg)	N=63		N=170		N=205		N=104		N=28	
♦ Mean ± SD	22.4 ± 7.4		18.9 ± 9.9		17.9 ± 11.4		16.4 ± 11.5		17.2 ± 11.2	
EOA (cm^2)	N=15		N=37		N=31		N=19		N=2	
♦ Mean ± SD	1.0 ± 0.3		1.3 ± 0.5		1.4 ± 0.5		1.9 ± 0.7		1.7 ± 0.4	
Regurgitation	21mm		23mm		25mm		27mm		29mm	
	n	%	n	%	n	%	n	%	n	%
♦ None	37	58.7	111	60.0	104	48.4	60	56.6	13	40.6
♦ Trivial	18	28.6	45	24.3	56	26.1	26	24.5	10	31.3
♦ Mild	6	9.5	16	8.7	29	13.5	14	13.2	3	9.4
♦ Moderate	1	1.6	12	6.5	19	8.8	4	3.8	6	18.8
♦ Severe	1	1.6	1	0.5	7	3.3	2	1.9	0	0.0
University of Padua Medical Center, Italy All Aortic Valve Replacements, N=313										
Hemodynamic Parameter	Results by Valve Size									
	21mm		23mm		25mm		27mm		29mm	
Data from the Follow-up interval ≥ 11 months										
Mean Gradient (mmHg)	N=40		N=93		N=61		N=12		N=1	
♦ Mean ± SD	18.8 ± 6.3		17.3 ± 7.6		15.2 ± 5.2		13.9 ± 4.8		11.00 ± NA	
EOA (cm^2)	N=36		N=88		N=59		N=9		N=1	
♦ Mean ± SD	1.3 ± 0.3		1.5 ± 0.3		1.5 ± 0.3		1.5 ± 0.2		3.3 ± NA	
Regurgitation	21mm		23mm		25mm		27mm		29mm	
	n	%	n	%	n	%	n	%	n	%
♦ None	34	79.1	84	90.3	56	91.8	10	83.3	1	100
♦ Trivial	7	16.3	8	8.6	4	6.6	2	16.7	0	0.0
♦ Mild	2	4.7	1	1.1	0	0.0	0	0.0	0	0.0
♦ Moderate	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0
♦ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

7. INDIVIDUALIZATION OF TREATMENT

7.1 Anticoagulant and/or Antiplatelet Therapy

Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

8. PATIENT COUNSELING INFORMATION

Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

Patients with bioprostheses who undergo dental or other procedures which are potentially bacteremic should receive endocarditis prophylactic antibiotic therapy.

Patients should be encouraged to complete the patient identification card provided with the valve and to carry it with them at all times.

St. Jude Medical publishes a patient brochure, "SJM Biocor® Valve / SJM Biocor® Supra Valve Patient Education Booklet," that may be available to the patient. Copies of this booklet are available through your SJM sales representative. A copy should be provided to each patient.

9. PACKAGING AND STORAGE

As delivered, the valve is attached to a valve holder by three retaining sutures. A flexible plastic support surrounds the valve. The valve holder and support facilitate handling and manipulation of the valve during removal from the container, rinsing, and implantation.

The valve is packaged in a formaldehyde storage solution. Store the valve in the upright position.

CAUTION: Do not implant the valve without thoroughly rinsing as directed.

Storage Temperature Indicator

The valve should be stored in temperatures from 5° to 25° C (41° to 77° F). Do not store the valve where significant temperature fluctuations may occur. If the valve has been exposed to extreme temperatures, the freeze indicator or heat indicator will turn red. If either indicator has turned red, do not use the valve.

CAUTION: Do not expose valves to extreme temperatures. Freezing or prolonged exposure to heat (45° C and above) may irreversibly damage the biological tissue. Valves that have been exposed to these temperature extremes, or that are suspected of being exposed to these temperature extremes, should not be used.

Sizers
Use only the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Model B807 with the SJM Biocor® Supra valve. See the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Model B807 Physician's Manual for specific instructions on cleaning, sterilization, and handling.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked or deformed sizers.

10. DIRECTIONS FOR USE

10.1 Pre-Implant Handling

The SJM Biocor® Supra valve is supplied in a storage container with a screw-cap closure and tamper-evident seal. The contents of the container are sterile, and must be handled aseptically to prevent contamination.

WARNING: Do not use the valve if the expiration date has elapsed.

WARNING: Do not use the valve if fluid is leaking from the packaging.

WARNING: Do not resterilize the valve by any method.

10.2 Removing the valve from the outer packaging

PRECAUTIONS:

- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline used to irrigate the valve.
- Do not add antibiotics to either the valve storage solution or the rinse solution.
- Do not apply antibiotics to the valve.

1. After sizing, choose a valve of the appropriate size.
2. Once the valve container has been removed from the outer packaging, examine the container for evidence of damage.

WARNING: The valve must not be implanted if the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging

WARNING: The valve must not be implanted if the storage solution does not completely cover the valve.

3. Verify the valve size and expiration date on the label.
4. To remove the valve from the container, break the seal and remove the screw-top closure.

Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

10.3 Removing the valve from the storage container

1. With the circulating nurse holding the container, screw the valve holder handle into the valve holder as shown in Figure 2, and remove the valve from the jar.

Figure 2 - Remove the valve using the valve holder handle.

CAUTION: Do not handle the valve with unprotected forceps or sharp instruments. Never handle the leaflet tissue.

2. Inspect the valve for damage.

WARNING: Do not implant the valve if the valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration.

10.4 Rinse procedure

CAUTION: Do not implant the valve without thoroughly rinsing as directed.

1. Within the sterile field prepare three sterile basins with a minimum of 500 ml of sterile isotonic saline in each basin.
2. Holding the valve by the handle, **fully immerse** the valve support, the valve, the valve holder, and the portion of the holder handle that was submerged in the valve storage solution, in the sterile isotonic saline solution in the first basin.
3. Continually rinse the valve for two minutes, using a gentle back-and-forth motion.
4. Repeat step three in each of the remaining two basins.
5. After rinsing, leave the valve immersed in the third basin until required by the surgeon for implantation.
6. Prior to implantation, remove the valve support by depressing the three tabs below the level of the valve support ring, as indicated in Figure 3.

Figure 3 - To release the valve support from the valve cuff, depress the three tabs at the base of the valve support below the support ring.

CAUTION: Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution.

10.5 Surgical Guidelines

The actual choice of surgical technique, modified in accordance with the instructions described herein, is left to the discretion of the individual surgeon.

10.6 Sizing

The SJM Biocor® Supra valve is designed for implantation in the supra- annular position. The flanged portion of the sizer mimics the placement of the sewing cuff on top of the annulus, Figure 4 .
The sizer barrel that fits snugly in the annulus is the sizer that identifies the valve that should be selected.

Figure 4- Sizing the valve

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked or deformed sizers.

WARNING: Valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical® Bioprosthetic Heart Valve Sizer Set Model B807 sizers for sizing of SJM Biocor® Supra valves.

CAUTION: Do not pass the flanged portion of the sizer through the annulus when sizing the valve.

NOTE: The sizer posts may be used to approximate placement of the valve in a manner such that the coronary ostia are not obstructed.

10.7 Valve Implantation

The SJM Biocor® Supra valve is designed for implantation in the supra- annular position.

1. Select a valve based on a sizer that fits snugly in the annulus.
2. Avoid any contact between the implantation sutures and the leaflets.

PRECAUTIONS:

- Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Position the valve so that the stent posts do not obstruct the coronary ostia.
- Do not lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced. Do not attempt to repair a valve. Damaged valves must not be used.
- Do not use cutting edge needles, since they may cause structural damage to the bioprosthesis.

3. To remove the holder from the valve, cut the three retaining sutures as shown in Figure 5, and pull the handle and the valve holder away from the valve. After removing the holder, examine the valve to ensure that there are no holder suture remnants.

Figure 5 - Aortic holder removal.

10.8 Intra-Operative Assessment

The suggested method for assessing competence of the SJM Biocor® Supra valve is with intra-operative Doppler echocardiography.

11. PATIENT REGISTRATION

A Medical Device Registration form is included with each device. After implantation, please complete all requested information, and return the original form to the address indicated on the Medical Device Registration form. Tracking by manufacturers is mandatory within the United States. For countries outside of the United States please disregard any request for patient information if this contradicts your local legal or regulatory requirements regarding patient privacy.

12. LIMITED WARRANTY

St. Jude Medical (SJM) warrants that reasonable care has been used in the manufacturing of this device. THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, since handling, storage, cleaning, and sterilization of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond SJM's control directly affect this device and the results obtained from its use. SJM SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE directly or indirectly arising from the use of this device other than the replacement of all or part of it. SJM neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Some states in the United States do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you. This limited warranty gives you specific legal rights, and you may have other rights which vary from jurisdiction to jurisdiction.

Descriptions of specifications appearing in SJM literature are meant solely to generally describe the device at the time of manufacture and do not constitute any express warranties.

Corporate Headquarters:
St. Jude Medical, Inc.
One Lillehei Plaza
St. Paul, Minnesota 55117 USA

Manufactured by:
St. Jude Medical Brasil Ltda.
Rua da Paisagem, 310B
Vila da Serra
Nova Lima-MG

CEP 34.000-000 Brazil

24-hour Technical Professional Consultation

Telephone: (800) 328-9634-U.S.A. Toll Free
(651) 483-2000
Fax: (651) 482-8318

Customer Service:

Telephone: (800) 544-1664-U.S.A. Toll Free
(651) 490-4410
Fax: (651) 481-7702

Brazilian patent 8402134-9

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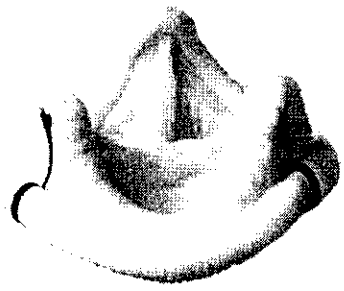
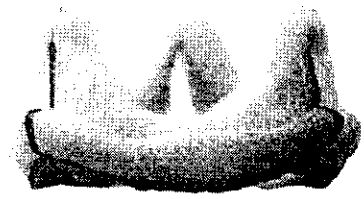
SJM Biocor® Valve
SJM Biocor® Supra Valve
Patient Education Booklet



SJM Biocor® Valve



SJM Biocor® Supra Valve

ST. JUDE MEDICAL

Glossary

Angina	Chest pain
Anticoagulation Medicine	Medication prescribed to prevent clot formation
Aorta	Primary artery which carries oxygenated blood to the body
Aortic Valve	Valve located between left ventricle and aorta
Arrhythmia	Abnormal heart rhythm
Atrial Fibrillation	An irregular heart rhythm in which many impulses begin and spread through the atria. The resulting rhythm is disorganized, rapid, and irregular and the atria are not able to fully empty their contents into the ventricles
Atrial Flutter	A regular heart rhythm in which many impulses begin and spread through the atria. The resulting rhythm is organized, but so rapid that the atria are not able to fully empty their contents into the ventricles.
Bioprosthetic Valve	Replacement heart valve which is made from animal tissue
Bovine	Of cow origin
Dilated	Enlarged
Dysrhythmia	Abnormal rhythm
Endocarditis	Infection of the heart's inner lining or valves
Explantation	Surgical removal of medical device
Hemolysis	Alteration or destruction of red blood cells with liberation of hemoglobin
Hemolytic Anemia	Anemia caused by excessive destruction of red blood cells
Hemorrhage	Excessive bleeding
Incompetent Valve	Valve unable to close completely, thus allowing blood to flow backwards through the valve
Mitral Valve	Valve located between left atrium and left ventricle
Native Valve	Original valve
Paravalvular Leak	Leak near the valve
Polyester Cloth	Man-made material used to create the sewing cuff used to secure the implanted valve to the tissue
Porcine	Of pig origin
Prosthetic	Device used to replace some part of the body
Pumping Efficiency	Ability of the heart to force blood into the body
Regurgitant Valve	Valve unable to close completely, thus allowing blood to flow backwards through the valve
Stenotic Valve	Narrowed or hardened valve that no longer opens completely
Stent	Plastic frame
Thromboembolism	Blood clot which travels through the bloodstream, eventually blocking a vessel
Thrombosis	Formation of a clot in the body
Valve	Structure which regulates flow
Valvular Pannus	Abnormally thick tissue around the valve

Your role in the management of your health is very important. We hope you find this booklet interesting and helpful when making these clinical decisions. This information is not intended to replace the medical advice of your physician. All medical treatment decisions should be made in consultation with and under the direction of your physician. If the information you receive from your physician differs from this brochure, always follow your physician's instructions.

Heart Chambers

Your heart is a muscular organ, slightly larger than your fist. It lies within your chest, just behind and to the left of your breast bone. The heart consists of four chambers. The upper, receiving chambers are called the atria (each chamber is called an atrium) and the lower, pumping chambers are the ventricles (Figure 1). Because of their pumping function, the ventricles are larger than the atria.

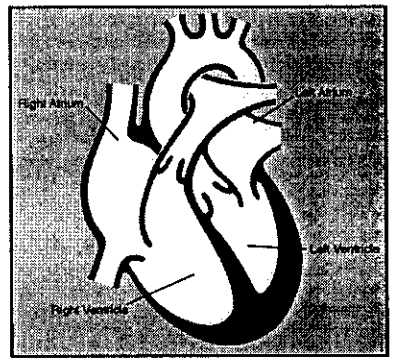


Figure 1
Chambers of the Heart

How Your Heart Works

The main job of the heart is to pump oxygen-rich blood through your body. It does this by contracting an average of 70 times per minute for a total of over 36 million heart beats per year.

Cardiac circulation begins in the right side of the heart. Veins return blood low in oxygen to the right atrium. Blood passes into the right ventricle where it is pumped into the lungs to receive oxygen. Oxygen-rich blood then re-enters the heart, moving into the left atrium. Blood then enters the left ventricle and is pumped out through the aorta and circulated to the rest of your body (Figure 2).

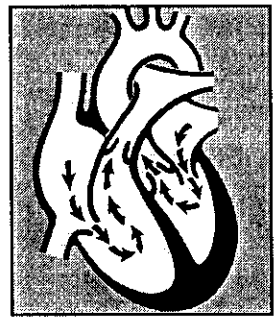


Figure 2
Cardiac Blood Flow

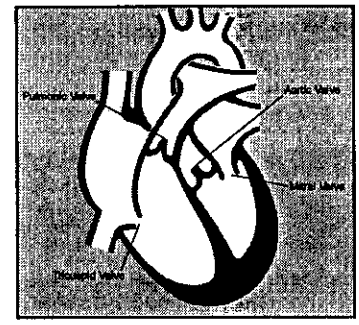


Figure 3
Heart Valves

Heart valves direct blood flow between the chambers of the heart. These valves act like one-way doors, allowing blood to flow forward into the next chamber. The valves close to prevent backflow.

On the right side of the heart, the blood flows through the tricuspid valve which lies between the atrium and the ventricle. On the left side of the heart, blood flows between the left atrium and the left ventricle through the mitral valve (Figure 3).

Valves also separate the ventricles and the large blood vessels that carry blood away from the heart. Blood flows through the pulmonic valve between the right ventricle and pulmonary artery and lungs. On the left side of the heart, blood flows through the left ventricle into the aorta through the aortic valve (Figure 3).

Valvular Heart Disease

Heart valves may be impaired for a variety of reasons. Some people are born with heart valve defects while others acquire valve damage from infection or other diseases. The results are the same: either a rigid valve limiting forward blood flow (called a stenotic valve) or a valve which does not close properly permitting backflow (called an incompetent or regurgitant valve).

The end result of valvular heart disease is the reduction in the heart's pumping ability. The heart tries to compensate for ineffective valve function by working harder to deliver oxygen-rich blood to other organs and tissues. The overworked heart may begin to fail, causing shortness of breath, dizziness, chest pains, fatigue, and fluid retention. After physical examination and further tests, physicians may recommend valve replacement.

Valve Replacement Options-Risks and Benefits

The first clinical replacement heart valve surgery took place in 1952. Since then, advances in technology have improved valve design and cardiac surgical technique, making heart valve replacement a common operation at most major hospitals. Today, there are several replacement valve options available within two broad categories of valve types, mechanical heart valves and bioprosthetic or tissue heart valves.

Mechanical heart valves are constructed with strong, man-made materials and designs. The most important benefit of mechanical valves is that they are the most durable of the valve types and are designed to last the lifetime of the patient. Patients with mechanical replacement heart valves must take daily blood anticoagulation medication to minimize the risk of complications from blood clots.

Bioprosthetic heart valves are made with tissue from porcine (pig) heart valves or bovine (cow) cardiac tissue. These tissue replacement heart valves are designed to function like natural heart valves. The most important benefit of this valve type is that the valve is very compatible with the blood stream. Patients with tissue valves are not always dependent on daily medication to minimize complications from blood clots.

Your physician can help you make the decision between a mechanical heart valve and a bioprosthetic heart valve. The decision may be based on your age, lifestyle, medication requirements, and other factors.

Risks

There are risks with any heart valve replacement. These may include, but are not limited to, blood cell damage (hemolysis), low red blood cell count (hemolytic anemia), bleeding, infection, clotting in or on the valve (thrombus formation), tissue on the valve (valvular pannus), loose clots in the blood stream that may block an artery in your arms, legs or brain (thromboembolism), valve failure (which may include structural damage), leakage around the edge of the valve (paravalvular leak), need for reoperation, explantation, arrhythmia, stroke, angina, heart failure, and death.

The SJM Biocor® Valve

The SJM Biocor® valve was first implanted in patients in 1981. The SJM Biocor® valve is a bioprosthetic heart valve intended for use as a replacement for a diseased, damaged, or malfunctioning aortic or mitral valve. The valve is manufactured using aortic valve tissue from pigs that has been chemically treated and prepared for human implantation. The SJM Biocor® valve is referred to as a stented tissue valve because the animal tissue is supported by a polyester covered plastic frame. A sewing cuff or ring, made of polyester cloth, is attached to the valve and enables the surgeon to sew the valve into place in the heart (Figure 4).

Figure 4
SJM Biocor® Valve

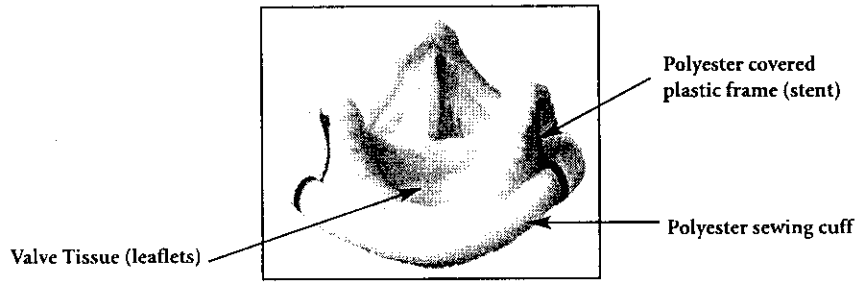
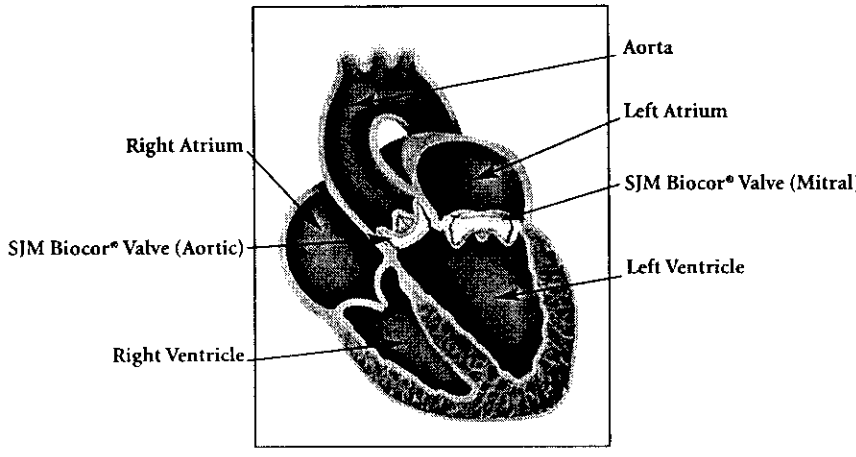


Figure 5
Position of Aortic and Mitral SJM Biocor® Valve in the Heart



The SJM Biocor® Supra Valve

The SJM Biocor® Supra valve is a bioprosthetic heart valve intended for use as a replacement for a diseased, damaged, or malfunctioning aortic valve. The valve is manufactured using aortic valve tissue from pigs that has been chemically treated and prepared for human implantation. The SJM Biocor® Supra valve is referred to as a stented tissue valve because the animal tissue is supported by a polyester covered plastic frame. A sewing cuff or ring, made of polyester cloth, is attached to the valve and enables the surgeon to sew the valve into place in the heart (Figure 6).

Figure 6
SJM Biocor® Supra Valve

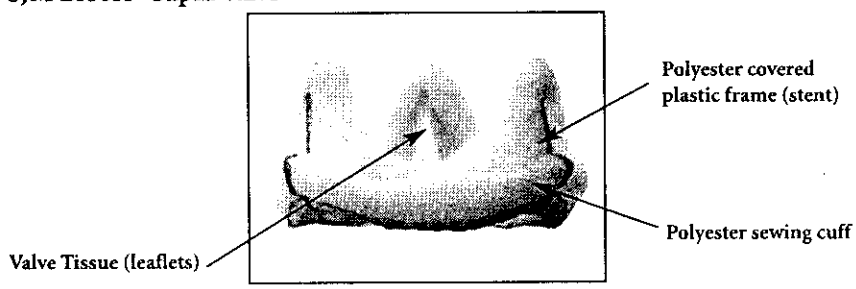
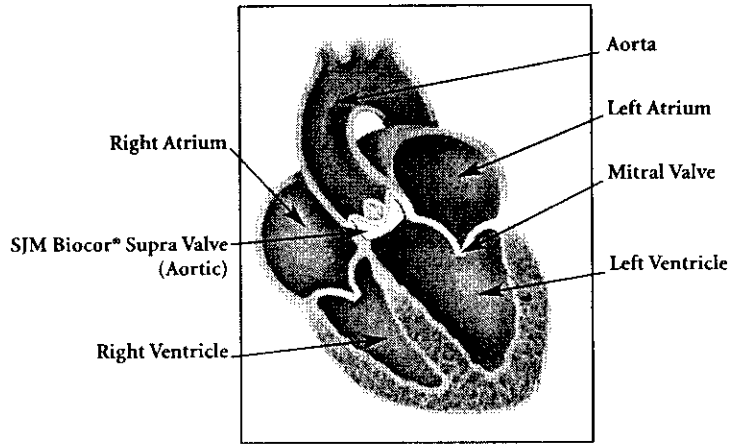


Figure 7
Position of Aortic SJM Biocor® Supra Valve in the Heart



Returning Home

Valve replacement does not mean a sedentary lifestyle. Many people who receive valves are able to lead a more active and fulfilling life than before surgery.

Your involvement in caring for the health of your heart begins now. By understanding the recovery process and life-long management necessary for your valve, you can make better heart-healthy decisions. Long-term management of your health requires your active participation. With your physician, you can work toward a healthy recovery.

Precaution: It is very important you heed the following advice.

Contact your physician(s) if you develop any of these symptoms:

- Redness or drainage of your incision
- Shortness of breath
- Swelling of your feet or ankles
- Chest, jaw, shoulder, or arm pain
- Bruising
- Excessive bleeding
- Blood in your urine
- Bloody or black tarry bowel movements
- Unusual nose bleeds
- Fever
- Numbness or tingling in your arms or legs
- General weakness or loss of energy
- Blurred or loss of vision
- Unusual chest sensation

A Hearty Reminder

Remember you are an important member of your health care team. The following will help you maintain a healthy heart.

Precaution: It is very important you heed the following advice.

- Report any signs of fluid retention to your doctor.
- It is very important to tell your dentist or physician you have an artificial heart valve because you will need to take antibiotics prior to any dental work or surgery to prevent infection of your heart valve.
- Take any medication as prescribed.
- Follow-up with blood tests as directed by your physician.
- Follow an exercise program as outlined by your physician.
- Enjoy a heart-healthy diet.
- If you are told you need to have an MRI or magnetic resonance image, tell the doctor you have an artificial heart valve, and show him/her your patient identification card. It contains important information about how to perform an MRI safely with your valve.

VISIT OUR WEB SITE AT www.sjm.com

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER. **The SJM Biocor® valve is indicated for use as a replacement for malfunctioning native or prosthetic valves. The SJM Biocor® Supra valve is indicated for use as a replacement for malfunctioning native or prosthetic aortic valves. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage (anticoagulant/antiplatelet-related), leak (transvalvular or paravalvular), myocardial infarction, nonstructural dysfunction (e.g. pannus, suture, inappropriate sizing, or other), prosthesis regurgitation, stroke, structural deterioration (e.g. calcification, leaflet tear, or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to: reoperation, explantation, permanent disability, or death. Long-term anticoagulation and/or anti-platelet therapy should be considered in patients with dilated left atrium, a history of thrombotic events, or a cardiac rhythm of atrial fibrillation or flutter. Please see the physician's manual for a full description of indications, contraindications, side effects, precautions, warnings, and instructions for use.**

Corporate Headquarters St. Jude Medical, Inc. One Lillehei Plaza, St. Paul, Minnesota 55117 USA **24-Hour Technical/Professional Consultation** (800) 328-9634 (USA) (651) 483-2000 Fax: (651) 482-8318 **Customer Service** (800) 544-1664 (USA) (651) 490-4410 Fax: (651) 481-7702 **European Headquarters** St. Jude Medical Europe, Inc., The Corporate Village, Avenue Da Vinci laan, 11-Box F1, B-1935, Zaventem, Belgium **Customer Service** Tel: 32-2-774-68-11 Fax: 32-2-772-83-84 **Asian Headquarters** St. Jude Medical Hong Kong Limited, Room 2705-2708, China Merchants Tower, Shun Tak Centre, 168-200 Connaught Road, Central, Hong Kong Tel: (852) 2996-7688 Fax: (852) 2956-0622 ITEM1757A/0505/20/EN/BD

The Global Leader in Heart Valve Devices.™

ST. JUDE MEDICAL

ST. JUDE MEDICAL

St. Jude Medical, Inc.
One Lillehei Plaza
St. Paul, MN 55117 / USA
Telephone 651-483-2000 1-800-344-5863 Fax 651-491-7873

MEDICAL DEVICE REGISTRATION FORM

ST. JUDE MEDICAL Patient Identification Card

PATIENT NAME:

SERIAL NUMBER: MODEL NUMBER:

MRI COMPATIBLE

IMPLANTING PHYSICIAN:

HOSPITAL:

IMPLANT DATE:

IMPORTANT: This device must be tracked in accordance with Section 519(e) of the Federal Food, Drug and Cosmetic Act and 21 CFR Part 821. Compliance by manufacturers is mandatory within the United States. Failure to comply could result in the imposition of a penalty by the federal government. NO PATIENT CONSENT OR AUTHORIZATION IS REQUIRED TO DISCLOSE INFORMATION TO MANUFACTURERS FOR TRACKING PURPOSES, in accordance with 45 CFR 164.512(b)(1)(iii)(B)(Regulations issued under the Health Insurance Portability and Accountability Act of 1996).

For countries whose laws or regulations prohibit the transfer of identifiable personal information to the United States under these circumstances, please complete only the gray shaded areas.

DEVICE / APPAREIL / HERZKLAPPE / DISPOSITIVO / DISPOSITIVO / デバイス

PRODUCT NAME / NOM DU PRODUIT / PRODUKTNAME / NOME DEL PRODOTTO / NOMBRE DEL PRODUCTO / 製品名

MODEL/SIZE / MODÈLE/DIMENSION / MODELL/GRÖSSE / MODELLO/DIMENSIONI / MODELO/TAMAÑO / 型番号

SERIAL NUMBER / NUMERO DE SERIE / SERIENNUMMER / NUMERO DI SERIE / NÚMERO DE SERIE / シリアル番号

DEVICE IMPLANTED? / L'APPAREIL A-T-IL ÉTÉ IMPLANTÉ ? / WURDE DIE KLAPPE IMPLANTIERT? / DISPOSITIVO IMPIANTATO? / ¿DISPOSITIVO IMPLANTADO? / 植込みを実施しましたか？ ☐ YES / OUI / JA / SI / SÍ / はい ☐ NO / NON / NEIN / NO / NO / いいえ

IF NO, PLEASE STATE REASON(S) BELOW: / SI NON, VEUILLEZ PRÉCISER LA (LES) RAISON(S) CI-DESSOUS : / WENN NEIN, BITTE UNTEN ANGEBEN, WARUM: / IN CASO NEGATIVO, PREGARSI INDICARNE DI SEGUITO LA RAGIONE O LE RAGIONI: / EN CASO NEGATIVO, INDICAR LOS MOTIVOS A CONTINUACIÓN: / いいえ / のときは、その理由を以下に記載してください。

PATIENT / PATIENT / PATIENT / PAZIENTE / PACIENTE / 患者

IMPLANT DATE / DATE D'IMPLANTATION / IMPLANTATIONSDATUM / DATA DI IMPIANTO / FECHA DE IMPLANTE / 植込み日: DAY / JOUR / TAG / GIORNO / DÍA / 日 ☐ MONTH / MOIS / MONAT / MESE / MES / 月 ☐ YEAR / ANNÉE / JAHR / ANNO / AÑO / 年 ☐

IMPLANT POSITION / POSITION DE L'IMPLANT / IMPLANTATIONSPOSITION / POSIZIONE DELL'IMPIANTO / POSICIÓN DE IMPLANTE / 植込み位置: A = AORTIC / AORTIQUE / AORTISCH / AORTICA / AÓRTICA / 大動脈弁 M = MITRAL / MITRALE / MITRAL / MITRALE / MITRAL / 僧帽弁 T = TRICUSPID / TRICUSPIDE / TRIKUSPIDAL / TRICUSPIDALE / TRICÚSPIDE / 三尖弁

LAST NAME / NOM / NACHNAME / COGNOME / APELLIDOS / 姓 | FIRST NAME / PRÉNOM / VORNAME / NOME / NOMBRE / 名 | INITIAL / INITIALE / 2E PRÉNOM / 2. VORNAME / INIZ. 2. NOME / INICIAL 2º NOMBRE / イニシャル

ADDRESS / ADRESSE / ADRESSE / INDIRIZZO / DIRECCIÓN / 住所 | P.O. BOX / APT. # / BTE / N. APPT. / POSTFACH/APP.-NR. / CAS. POST. / N. APT. / APDO. POSTAL / 郵便私書箱/号 | TELEPHONE / NUMERO DE TELEFONO / TELEFON / TELEFONO / TELÉFONO / 電話番号

CITY / VILLE / STADT / CITTÀ / CIUDAD / 市町村名 | STATE/ DÉPARTEMENT/ BUNDESLAND / STATO / PROVINCIA / 県名 | ZIP CODE / CODE POSTAL / POSTLEITZAHL / CAP / CÓDIGO POSTAL / 郵便番号 | COUNTRY / PAYS / LAND / PAESE / PAÍS / 国名

AGE / ÂGE / ALTER / ETÀ / EDAD / 年令 ☐ DATE OF BIRTH / DATE DE NAISSANCE / GEBURTSDATUM / DATA DI NASCITA / FECHA DE NACIMIENTO / 生年月日 DAY / JOUR / TAG / GIORNO / DÍA / 日 ☐ MONTH / MOIS / MONAT / MESE / MES / 月 ☐ YEAR / ANNÉE / JAHR / ANNO / AÑO / 年 ☐

MALE / MASCULIN / MÄNNLICH / MASCHIO / HOMBRE / 男 ☐ FEMALE / FÉMININ / WEIBLICH / FEMMINA / MUJER / 女 ☐

SOCIAL SECURITY NUMBER

HEALTHCARE FACILITY / CENTRE CHIRURGICAL / KRANKENHAUS / ISTITUTO SANITARIO / CENTRO MÉDICO / 医療機関

HOSPITAL / NOM DU CENTRE / NAME DES KRANKENHAUSES / CENTRO OSPEDALIERO / NOMBRE DEL CENTRO / 病院名

CITY / VILLE / STADT / CITTÀ / CIUDAD / 市町村名 | STATE / DÉPARTEMENT / BUNDESLAND / STATO / PROVINCIA / 県名 | ZIP CODE / CODE POSTAL / POSTLEITZAHL / CAP / CÓDIGO POSTAL / 郵便番号 | COUNTRY / PAYS / LAND / PAESE / PAÍS / 国名

IMPLANTING PHYSICIAN / CHIRURGIEN / CHIRURG / CHIRURGO / CIRUJANO / 執刀医

LAST NAME / NOM / NACHNAME / COGNOME / APELLIDOS / 姓 | FIRST NAME / PRÉNOM / VORNAME / NOME / NOMBRE / 名 | INITIAL / INITIALE / 2E PRÉNOM / 2. VORNAME / INIZ. 2. NOME / INICIAL 2º NOMBRE / イニシャル

FOLLOWING PHYSICIAN / MÉDECIN TRAITANT / BEHANDELNDER ARZT / MEDICO CURANTE / MÉDICO DE SEGUIMIENTO / 経過観察責任医師

LAST NAME / NOM / NACHNAME / COGNOME / APELLIDOS / 姓 | FIRST NAME / PRÉNOM / VORNAME / NOME / NOMBRE / 名 | INITIAL / INITIALE / 2E PRÉNOM / 2. VORNAME / INIZ. 2. NOME / INICIAL 2º NOMBRE / イニシャル

ADDRESS / ADRESSE / ADRESSE / INDIRIZZO / DIRECCIÓN / 住所 | CITY / VILLE / STADT / CITTÀ / CIUDAD / 市町村名

STATE / DÉPARTEMENT / BUNDESLAND / STATO / PROVINCIA / 県名 | ZIP CODE / CODE POSTAL / POSTLEITZAHL / CAP / CÓDIGO POSTAL / 郵便番号 | COUNTRY / PAYS / LAND / PAESE / PAÍS / 国名 | TELEPHONE / NUMERO DE TELEFONO / TELEFON / TELEFONO / TELÉFONO / 電話番号

ST. JUDE MEDICAL, One Lillehei Plaza, St. Paul, MN 55117

ST. JUDE MEDICAL

IMPORTANT
FOR ALL IMPLANTS IN THE UNITED STATES

TRACKABLE DEVICE

This device must be tracked in accordance with Section 519(e) of the Federal Food, Drug and Cosmetic Act and 21 CFR Part 821. Compliance by manufacturers is mandatory within the United States. Tracking is required in order to assure appropriate remedial action can be taken immediately if the FDA determines there is a reasonable probability that a device would cause serious adverse health consequences or death.

Note: St. Jude Medical may use the information on this form to periodically contact patients and verify the accuracy of the data supplied, as well as provide educational information to patients about their medical device or related products.

INSTRUCTIONS FOR THE UNITED STATES AND CANADA:

- Complete all information requested on the form. **Please type or print legibly.**
- If desired, complete the temporary Patient Identification Card and give it to the patient before they leave the hospital. A permanent card will be issued when this completed registration form is received and processed.
- **Return the original Medical Device Registration Form** with the implant information in the enclosed postage-paid envelope and retain the copies.
- If you have any questions, please **call 1-800-344-JUDE (5833).**
- **In the United States, no patient consent or authorization is required to disclose information to manufacturers for tracking purposes, in accordance with 45 CFR 164.512(b)(iii)(B) (Regulations issued under the Health Insurance Portability and Accountability Act of 1996).**

INSTRUCTIONS POUR LES ÉTATS-UNIS ET LE CANADA :

- Fournissez toutes les informations demandées sur le formulaire. **Veuillez écrire ou taper les caractères lisiblement.**
- Si besoin est, complétez la Carte temporaire d'identification du patient et donnez-la-lui avant qu'il ne quitte l'hôpital. **Une carte permanente sera délivrée après réception et traitement de ce formulaire d'inscription dûment complété.**
- **Renvoyez l'original du Formulaire d'enregistrement de l'appareil médical,** accompagné des renseignements sur l'implant, dans l'enveloppe prépayée ci-jointe et conservez-en des copies.
- Pour toute question, veuillez composer le numéro suivant : 1-800-344-JUDE (5833).
- **Aux États-Unis, le consentement ou l'autorisation du patient n'est pas nécessaire pour divulguer des informations aux fabricants à des fins de suivi, conformément au code 45 CFR 164.512(b)(iii)(B) (réglementation parue en vertu du décret HIPAA (Health Insurance Portability and Accountability Act) de 1996).**

INSTRUCTIONS FOR ALL OTHER COUNTRIES:

- If desired, complete the attached Patient Identification Card and give it to the patient before they leave the hospital.
- If you would like St. Jude Medical to enter the implant information into its device tracking database, complete the Medical Device Registration Form and return it to St. Jude Medical taking into account the following:
  - If your country laws or regulations prohibit the collection, processing and transfer of identifiable personal information to the United States without the explicit consent of the patient, please **complete only the gray shaded areas.**
  - If country regulations permit the collection, processing and transfer of identifiable personal information to the United States without the explicit consent of the patient, please complete ***all*** areas.
- Hospitals or physicians should maintain implant information as appropriate.
- If you have any questions, please contact your St. Jude Medical representative.

ST. JUDE MEDICAL Patient Identification Card

PATIENT NAME:

SERIAL NUMBER: MODEL NUMBER:

THIS IS NOT AN INSURANCE CARD

IMPLANTING PHYSICIAN:

HOSPITAL:

IMPLANT DATE:

www.sjm.com, USA Phone 651.483.2000 or 1.800.344.5833(JUDE)

PLEASE CONTACT YOUR PHYSICIAN FOR MEDICAL QUESTIONS

St. Jude Medical, One Lillehei Plaza, St. Paul, MN 55117-1799
It is important that St. Jude Medical Patient Device Tracking records be updated if any of your information changes.
Please contact us toll-free or at our Web site.

MRI Safety Information:

Non-clinical testing has demonstrated that SJM heart valves are MR safe under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient of 325 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning

SJM heart valves produce a temperature rise of less than or equal to 0.5 °C under the conditions listed above. SJM heart valves can be scanned safely under the conditions listed above.
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the SJM heart valve.